REMARKS

The Rejection Under 35 USC § 112, first paragraph (written description)

The Office Action alleges that "applicants are not in possession of all compounds encompassed by formula I," but only of compounds having substituents as defined on page 2 of the Office Action, which substituents list appears to have been formulated in view of the examples (see also the allegations at the top of page 4 in this regard).

The Office Action proceeds to cite a large number of relevant decisions, but fails to make allegations in view thereof, e.g., the Office Action fails to apply the law to the situation in the present case. Thus, the Office Action has not carried its burden in establishing the alleged lack of written description. For example, the Office Action failed to explain why one of ordinary skill in the art would find that applicants were not in possession of the claimed invention, especially when the specification provides a very large amount of guidance and hundreds of examples as discussed below. Thus, even for this reason alone, this rejection cannot be maintained.

Moreover, just because the group of compounds recited in the claims is broader than compounds specifically exemplified in the application does not mean that the scope of the invention would be determined by one of ordinary skill in the art to be limited to the exemplified compounds, especially in view of the vast amount of disclosure.

Applicants on pages 7 to 10 provide numerous reaction schemes by which one of ordinary skill in the art could prepare the compounds of the present invention, and not only the compounds specifically exemplified. On pages 20-23 applicants provide further reaction schemes, reaction conditions, etc., and cite reference(s) which would provide one of ordinary skill in the art with further details on the known methods of preparation of the claimed compounds. Applicants also disclose that other similar compounds are known in the field at the bottom of page 3 and cite several patent documents. The application additionally provides over 700 exemplified compounds. In view of the disclosure, one of ordinary skill in the art in view of what was known at the time of filing would understand that applicants were in possession of the claimed invention to its fully claimed and described scope, including of compounds not specifically exemplified.

For all the foregoing reasons, reconsideration of all the rejections is respectfully requested.

The Rejection Under 35 USC § 112, first paragraph (enablement)

The Office Action admits that the specification enables the in vitro binding of compounds to 5-HT_{2A}, but alleges that it does not provide enablement for the treatment of diseases.

There is absolutely no basis for these allegations. The only substantive allegations of the Office Action are the citations to Wood at al. and Crow on page 5 of the Office Action. However, the disclosures have been inaccurately characterized, and the further allegation based thereon on page 6 of the Office Action, that there is "high unpredictability in the art as evidenced herein," also has no basis.

Wood et al. is cited to "teach that therapeutic efficacy remains to be seen for modulation of serotonin receptors." The Office Action fails to mention that this reference deals only with depression, and not any other indications. Additionally, applicants did not find the exact alleged teaching in Wood et al., but found that the abstract teaches that "selective serotonin re-uptake inhibitors which are widely used in the treatment of depression and depressive disorders," and that "it was suggested that serotonin antagonists should induce similar neuroadaptive changes." The reference provides an overview of the "profiles of novel serotonin antagonists currently in preclinical development." The overview demonstrates that certain successes have already been achieved. See, e.g., the reference to Nefazodone, a relatively new antidepressant from Bristol-Myers Squibb, which has 5-HT re-uptake inhibition and 5-HT2A receptor antagonistic activity, and is described as "in the clinic, nefazodone is an effective antidepressant." See the last paragraph on page 460.

Crow is alleged to teach in the "Conclusion" section that "eating disorders cannot be treated by drugs alone." This was not found in the conclusion of Crow. Instead, the following disclosure is present therein "Pharmacological treatments currently used for the treatment of eating disorders are helpful … Many potentially useful compounds are in development. Some are serotonin agents, similar in some respect to those already in use."

Additionally, whether eating disorders can or cannot be treated with "drugs alone" is irrelevant to the present claims. The claims do not recite the treatment being accomplished by drugs alone. Moreover, the fact that drugs (whether alone or not) can treat eating disorders only leads to the conclusion that the present claims are enabled, and do not at all support the allegations by the Office Action.

The Office Action also alleges that the specification provides no guidance. That is also an inaccurate characterization of the disclosure. On page 4, the activity of the

compounds is disclosed with reference to tests on in-vitro affinity of the claimed compounds with citation to references. Further in vitro tests are provided on page 5 of the specification with citations to references. Also disclosed on page 5 (middle of page) is how the in vivo 5-HT_{2A}-antagonistic property of the compounds can be determined with citation to references. From the bottom of page 5 to the bottom of page 6 numerous references are cited disclosing indications having a nexus to the claimed activity. Additionally, dosage information and formulations are disclosed on pages 23-24, and many are exemplified on pages 77-79.

Thus, none of the allegations have basis upon which the lack of enablement rejection is based. Nevertheless, the following comments are provided.

In a proper enablement rejection, first and foremost, a specification disclosure which "contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (1971). "The PTO must have adequate support for its challenge to the credibility of applicant's statements of utility". (The quoted statement was made in the context of enablement, i.e., the how-to-use requirement of the first paragraph of section 112.) See also *In re Bundy*, 209 USPQ 48 (1981). The only relevant concern of the Patent Office should be over the truth of assertions relating to enablement. The first paragraph of section 112 requires nothing more than objective enablement. See *In re Marzocchi, supra.*

The Examiner has not established any basis to doubt objective enablement. The Examiner has also provided no support for establishing that one of ordinary skill would doubt the objective truth of the asserted utility, which is enabled by the specification. The enablement rejections by the Examiner are thus unfounded. The rejection therefore was improper under *In re Marzocchi.*

The claims rejected are directed to the treatment of indications well known and known to be associated with serotonin receptors, the treatment of which are not objectively doubtable. There is no indication that one of ordinary skill in the art would have questioned the effect of the drugs in view of the disclosure and the state of the art. See *Rasmusson v. Smithkline Beecham Co.*, 75 USPQ2d 1297 (Fed. Cir. 2005).

As discussed above, this is adequate to objectively enable an invention.

Moreover, the state of the art is quite well developed as can be clearly seen even from

the references cited by the Office Action. Thus, one of ordinary skill in the art has a great amount of knowledge where many drugs with similar activities are in clinical phases of development. Thus, with the current state of the art at the time of filing there is no basis for a rejection for lack of enablement.

Applicants provided adequate support and evidence to enable the method claims. Reconsideration is respectfully requested.

The Rejection Under 35 USC § 112, second paragraph (indefiniteness)

The Office Action alleges that it is unclear what disease is intended to be treated in claim 11 and what neurological disorder is referred to in claim 16.

One of ordinary skill in the art knows based on the prior art (which is abundant as reflected by the citations in the specification), and/or can test (with many tests available and also described in the specification) which diseases and which neurological disorders (many specifically identified in the specification) can be influenced by the binding of a compound to 5 HT receptors. Thus, there is no indefiniteness.

The rejection appears to wish these claims restricted to specific indications for lack of definiteness, whereby this rejection appears to be merely to the breadth of these claims.

However, even in cases where the breadth of a claim may be undue, which is not the case here, nor is admitted to be, courts have held that "undue breadth of claims is not indefiniteness." See *In re Borkowski*, 422 F.2d 904, 164 USPQ 642 (CCPA 1970). Merely because a claim describes a general class of diseases that may contain a large or great number of specific diseases, such is not a valid reason for rejecting said claim as indefinite.

Reconsideration of the rejections is respectfully requested.

The Office Action also rejects the term "Het" and alleges that it is unclear what it stands for. The issue here too appears to be not the lack of clarity in view of the Office Action even proposing an understanding of the scope of this term, but breadth.

"If scope of subject matter embraced by claim is clear, … then claim does particularly point out and distinctly claim subject matter that applicant regards as his invention … [thereby] not render[ing] claim imprecise or indefinite or otherwise not in compliance with second paragraph of Section 112." See *In re Hyatt*, 218 USPQ 195 (CAFC 1983).

The examiner has not articulated any reason why one of ordinary skill in the art would have any difficulty ascertaining the metes and bounds of this claim. See *Ex parte Balzarini*,

21 USPQ2d 1892 (BPAI 1991) (holding that the term "human cells" is broad as observed by the examiner, reading upon human cells found in either an *in vitro* cell culture or in a living body; however, holding that the breadth of this term does not render the claims indefinite because examiner has not articulated any reason why one of ordinary skill in the art would have any difficulty ascertaining the metes and bounds of the claims.) Likewise, the present claims are also not indefinite.

See also *In re Johnson*, 194 USPQ 187 (CCPA 1977) (Holding the undefined "sigma a5value" definite because those skilled in the art would be able to determine immediately from the specification what level of activation (i.e., sigma a5value) is necessary to practice the invention.) The specification in this case provides clear and detailed guidance to those of ordinary skill in the art to determine whether a group is a Het group by, e.g., providing numerous exemplary Het groups and exemplary compounds having said feature.

Moreover, even in cases where the breadth of a claim may be undue, which is not the case here, nor is admitted to be, courts have held that "undue breadth of claims is not indefiniteness." See *In re Borkowski*, 422 F.2d 904, 164 USPQ 642 (CCPA 1970). Merely because a claim describes a general class of Het groups that may contain a great number of species, is not a valid reason for rejecting said claim as being indefinite.

Additionally, applicants point to the specification where numerous preferred Het groups are disclosed (see pages 12-17), and numerous (hundreds) exemplary compounds are provided having the claimed feature described. "Claim language must be read in light of the specification as it would be interpreted by one of ordinary skill in the art." See *In re Johnson*, supra.

Reconsideration of the rejections is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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Date: May 11, 2009

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